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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION N |
|----------------------------------|-------------|----------------------|---------------------|----------------|
| 09/908,070 | 07/18/2001 | Dachuan Yang | S63.2-9826 | 7520 |
| 490 | 7590 | 10/04/2004 | EXAMINER | |
| VIDAS, ARRETT & STEINKRAUS, P.A. | | | BAXTER, JESSICA R | |
| 6109 BLUE CIRCLE DRIVE | | | ART UNIT | |
| SUITE 2000 | | | PAPER NUMBER | |
| MINNETONKA, MN 55343-9185 | | | 3731 | |

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/908,070

Applicant(s)

YANG ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) 41 and 42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-14 is/are allowed.
- 6) ☒ Claim(s) 1,3-11,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09202001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 41 and 42 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are of a different species than previously claimed. Different fluorescing agents that were not previously claimed are now being claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41 and 42 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

2. Claim 4 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840 in view of U.S. Patent No. 5,082,630 to Partin et al.

Tingey discloses a method for detecting the presence and uniformity of a lubricious coating on a medical device comprising the steps of preparing a mixture of at least one fluorescing agent and at least one lubricant; applying said mixture to the surface of a medical device, subjecting the surface of the medical device to a source of energy capable of inducing a fluorescing emission; and observing the fluorescent emission (Column 2 line 64-Column 3 line 7). Tingey discloses the claimed invention except for the specific fluorescing agent being a fluorescein or a rhodamine. Partin teaches that fluorescein and rhodamine are fluorescent dyes that have good absorption and fluorescent yield characteristics that provide high sensitivity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device, of Tingey with a rhodamine or a fluorescein fluorescent agent since these agents have good absorption and fluorescent yield characteristics.

Regarding claims 3 and 4, Tingey discloses that said fluorescing agent is a fluorescein, triarylmethane, rhodamine, a derivative thereof, and mixtures thereof (Column 3 lines 56-61) and said hydrophilic dye is 5-carboxyfluorescein, 6-carboxyfluorescein, fluorexon, lissamine green, indocyanine green, rose bengal or mixture thereof (Column 4 line 56-Column 5 line 16).

Regarding claim 5, Tingey discloses that said hydrophobic lubricant is a silicone based lubricant (Column 3 lines 56-61).

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Regarding claim 6, Tingey discloses that said hydrophobic lubricant is a polydimethylsiloxane (Column 3 lines 56-61).

5. Claims 4, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al., as applied above, and further in view of U.S. Patent No. 5,346,689 to Peyman et al.

Tingey, as modified, discloses the claimed invention except for the specific fluorescing agent being a carboxyfluorescein. Peyman teaches that carboxyfluorescein is a hydrophilic derivative of fluorescein that is well known in the art to be used in applications to blood vessels that require fluorescent agents (Column 1 lines 42-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Tingey, as modified, with the fluorescing agent of a carboxyfluorescein since it is well known to be used in the surgical arts.

6. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840 in view of Partin et al. '630, as applied above, further in view of U.S. Patent No. 6,254,634 to Anderson et al.

Tingey, as modified discloses the claimed invention except for the use of a lubricant in combination with a crosslinkable silicone. Anderson teaches that an intermediate layer of crosslinkable silicone is provided with a coating in order to improve the performance or durability of the coating (Column 3 lines 41-62 and Column 5 lines 42-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Tingey, as modified, with the crosslinkable silicone in order to improve the durability of the coating on the medical device.

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7. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tingey et al. '840, in view of Partin et al. '630, as applied above, further in view of U.S. Patent No. 5,266,359 to Spielvogel.

Tingey, as modified, discloses the claimed invention except for the mixture further comprising a surfactant. Spielvogel teaches that a surfactant may be added to a medical device in order to improve the lubriciousness of the device (Column 2 lines 49-56 and Column 4 lines 38-52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Tingey with the surfactant of Spielvogel in order to improve the lubricity of the device.

Response to Arguments

8. Applicant's arguments with respect to claims 1 and 3-11 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

9. Claims 12-14 are allowed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2154. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


jrb

September 30, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

7/30/04